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| Appellant: | Haefner | Examiner: | Kahelin, M. |
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| Title: | IMPLANTABLE DEVICE WITH CARDIAC EVENT AUDIO PLAYBACK | | |

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# AMENDED APPEAL BRIEF

Mail Stop Appeal Brief - Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amended Appeal Brief is submitted pursuant to 37 C.F.R. §41.37(d) for the above-referenced patent application in response to the Notification of Non-Compliant Appeal Brief dated January 23, 2007. However, for future guidance, Appellant respectfully requests clarification as to the basis for the issuance of the Notice of Non-Compliance. The Notice asserts that dependent "means" claims were argued separately in the originally filed brief and were not properly included in the Summary of the brief. The meaning of "argued separately" appears to be set forth in 37 C.F.R. §41.37(c)(vii) as a claim being argued separately from the group of claims rejected under the same ground of rejection. According to this definition, none of the dependent "means" claims were argued separately in their respective grounds of rejection. Any clarification of this issue would be most appreciated.

The only differences between this Amended Appeal Brief and the Appeal Brief submitted on September 29, 2006 are this cover page and the discussions of dependent Claims 45-48 in the Summary (Section V).

No fee is believed to be required for the filing of this Amended Appeal Brief; however, if it is determined that a fee is necessary, authority is given to charge/credit deposit account 50-3581 (GUID.609PA) in support of this filing.

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## I. REAL PARTY IN INTEREST


The real party in interest is the assignee, Cardiac Pacemakers, Inc.

## II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

## III. STATUS OF CLAIMS

Claims 1-48 are pending, each of which is presented for appeal. Each of the pending Claims 1-48 has been finally rejected by the Examiner's action dated February 17, 2006, from which Appellant appeals.

The pending Claims 1-48 under appeal may be found in the attached Claims Appendix.

## IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated February 17, 2006.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is generally directed to cardiac monitoring and/or stimulation methods and systems that, in general, provide for acquisition of audio and electrical signals associated with cardiac activity, such as during cardiac monitoring and/or therapy delivery. Embodiments of the present invention are directed to methods and systems that involve acquisition of audio and electrical signals associated with cardiac activity by a patient-implantable device, and telemetering the audio and electrical signals from the patient-implantable device to a patient-external device. The patient-external device preferably includes a user interface configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal.

One embodiment of the present invention is directed to an implantable device. *See, e.g.*, Claim 1, Figs. 1A-C, and the corresponding discussion in the instant Specification at page 13, line 3 – page 20, line 20. The device includes an implantable housing (*e.g.*, 102) and a plurality of implantable electrodes (*e.g.*, 214 and 207) coupled to the housing and configured for sensing cardiac electrical activity. Detection circuitry (*e.g.*, 202) is provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity. An implantable sensor (*e.g.*, 261) is configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement. Sensor circuitry (*e.g.*, 204) is provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal. Memory (*e.g.*, 209) is provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal. A controller (*e.g.*, 205) is also provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry. Communications circuitry (*e.g.*, 218) is provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal to a patient-external device.

Other embodiments may be directed to a medical system that includes the above-discussed implantable device and a patient-external device. *See, e.g.*, Claim 17, Fig. 1E and the corresponding discussion in the instant Specification at page 22, line 23 – page 27, line 10. The patient-external device (*e.g.*, 420) includes patient-external communications circuitry configured to receive the cardiac electrical signal and the audio signal telemetered from the

patient-implantable device and a user interface coupled to the patient-external communications circuitry configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal (*e.g.*, page 24, line 22 – page 25, line2; page 30, lines 20-26).

Another embodiment of the present invention is directed to a method for cardiac monitoring. *See, e.g.*, Claim 32, Fig. 2, and the corresponding discussion in the instant Specification at page 27, line 11 – page 29, line 2. The method includes sensing, from within a patient, movement of a heart and producing a sensor signal in response to the sensed heart movement. An audio signal is produced, within the patient, using the sensor signal. Cardiac electrical activity is detected and a cardiac electrical signal is produced in response to the detected cardiac electrical activity, within the patient. The audio signal and the cardiac electrical signal are stored within the patient and the audio signal and the cardiac electrical signal are telemetered to a patient-external location.

Another embodiment of the present invention is directed to an implantable device. *See, e.g.*, Claim 44, Figs. 1A-C, and the corresponding discussion in the instant Specification at page 13, line 3 – page 20, line 20. The device includes means for detecting a cardiac signal and means for detecting cardiac non-electrophysiologic activity transduceable to an audio signal. The device also includes means for storing the cardiac electrical signal and the audio signal within a patient (*e.g.*, memory 209) and means for communicating the cardiac electrical signal and the audio signal to a patient-external location. The means for detecting a cardiac signal may include, for example: subcutaneous electrodes, *e.g.*, 214; can or indifferent electrodes, *e.g.*, 207; electrode subsystems, *e.g.*, 504, that may include coil electrodes, tip electrodes, ring electrodes, multi-element coils, spiral coils, spiral coils mounted on non-conductive backing, screen patch electrodes, and other electrode configurations; electrode arrays; processing circuitry 316; sensors, *e.g.*, 441, 442, 445, 446; and ECG electrodes used in connection with detection circuitry, *e.g.*, 202, 302; sensing circuitry, *e.g.*, 204, and a control system, *e.g.*, 205. The means for detecting cardiac non-electrophysiologic activity may include, for example: subcutaneous, cutaneous and/or external sensors; a sensor configured to sense pressure waves produced by heart movement; a piezoelectric transducer; a microphone situated in or on the housing, or in or on a lead; blood oxygen sensors; blood volume sensors; acoustic sensors and/or pressure transducers including, *e.g.*, diaphragm based acoustic sensors, MEMS-based

acoustic sensors such as a MEMS-based acoustic transducer, fiber optic acoustic sensors, piezoelectric sensors, and accelerometer-based acoustic sensors and arrays; accelerometers; processing circuitry, *e.g.*, 318; audio sensor, *e.g.*, 502; and phonocardiogram transducers used in connection with detection circuitry, *e.g.*, 202, 302; sensing circuitry, *e.g.*, 204, and a control system, *e.g.*, 205. The means for communicating the cardiac electrical signal and the audio signal include, for example: communications circuitry, *e.g.*, 218; short-range wireless communication interfaces such as Bluetooth and IEEE 802 communication interfaces; proprietary wireless protocols; an APM system, *e.g.*, 440; wire loop antennas; radio frequency telemetric links).

The above embodiment may also include means for playing back the cardiac electrical signal and the audio signal, means for concurrently displaying a representation of the cardiac electrical signal and broadcasting the audio signal, means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio signal in real-time, and means for providing server access to the cardiac electrical signal and the audio signal. *See, e.g.*, Claims 45-48, Fig. 1E, and the corresponding discussion in the instant Specification at page 22, line 23 – page 27, line 10. The means for playing back the signals include, for example: an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient external device (*e.g.*, 420), audio output devices, speakers, visual displays such as a monitor or other signal display device, patient input/trigger devices, memory, computers (remote or local), and terminals (*e.g.*, 450). The means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio in real-time or otherwise include, for example: an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient external device (*e.g.*, 420), telecommunications and information technologies, time correlation devices, audio output devices, speakers, visual displays such as a monitor or other signal display device, patient input/trigger devices, memory, computers (remote or local), and terminals (*e.g.*, 450). The means for providing server access include, for example, an advanced patient management medical system (*e.g.*, 440), medical device programmers (*e.g.*, 460, 470), patient information server (*e.g.*, 430), at least one database, and a network. Appellant also notes that a single structure may correspond to multiple "means" limitations. *See, e.g.*,

*Winbond Electronics Corp. v. International Trade Commission*, 4 Fed.Appx. 832, C.A.Fed., 2001.

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39 and 44 stand rejected under 35 U.S.C. §102(b) over Schaldach (U.S. Patent No. 4,867,163).

B. Claims 17, 19-21, 41, 45 and 46 stand rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) over Schaldach.

C. Claims 4 and 36 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Turcott (U.S. Patent No. 6,477,406).

D. Claims 8, 11 and 40 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Kadhiresan (U.S. Patent No. 5,935,081).

E. Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Gessman (U.S. Patent No. 5,321,618).

F. Claims 15, 26-29, 42 and 48 stand rejected under 35 U.S.C. § 103(a) over Schaldach in view of Riff *et al.* (U.S. Publication No. 2002/0026223).

## VII. ARGUMENT

In view of the alternative grounds of rejection presented with respect to Claims 17, 19-21, 41, 45 and 46, as set forth in Ground B in the previous section, Appellant addresses each of the rejections based upon §102(b), including the rejection of Claims 17, 19-21, 41, 45 and 46, in Section A below.

### A. The rejection under 35 U.S.C. §102(b) of Claims 1-3, 5-7, 9, 10, 12, 13, 16, 17, 19-21, 25, 30, 32, 35, 37-39, 41 and 44-46 is improper because Schaldach fails to teach each of the claimed limitations.

Each of independent Claims 1, 17, 32 and 44 include limitations directed to communicating both a cardiac electrical signal and an audio signal representative of a cardiac non-electrophysiologic activity (*e.g.*, heart movement) to a patient-external location. Appellant maintains that Schaldach does not teach, at least, the claimed communication of both signals to a patient-external device.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the patent claim; *i.e.* every element of the claimed invention must be literally present, arranged as in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain the rejection based on 35 U.S.C. §102. Appellant respectfully submits that Schaldach does not teach every element of independent Claims 1, 17, 32 and 44 in the requisite detail, and therefore fails to anticipate Claims 1-3, 5-7, 9, 10, 12, 13, 16, 17, 19-21, 25, 30, 32, 35, 37-39, 41 and 44-46.

Appellant maintains the traversal of the §102(b) rejection because the Examiner has not identified where Schaldach teaches communicating an audio signal that represents a cardiac non-electrophysiologic activity to a patient-external location. Schaldach does not use the term "audio" anywhere in its disclosure. The term "acoustic" is used once by Schaldach to describe a type of receiver that detects the presphygmic period and systolic discharge time. There is no indication that these timing variables are detected as audio signals nor that they are communicated to a patient-external device. Moreover, Schaldach describes control unit 150

(the asserted patient-external device) as having only a graphical display – there is no indication that the control unit 150 receives an audio signal or provides an audio output. Appellant fails to recognize, and the Examiner has not identified, where Schaldach teaches communicating an audio signal to a patient-external device. Without a presentation of correspondence to each of the claimed limitations, the §102(b) rejection is improper.

The Examiner asserts in the Advisory Action that Schaldach teaches displaying various combinations of 'characteristic fields' on an external device (column 23, line 59) where the 'characteristic fields' are input variables (column 23, lines 39) that include signals from sound pickups (column 7, line 61) and cardiac electrical activity (column 8, line 1; column 7, lines 31-68) and that such teaching corresponds to the claimed communicating of a cardiac electrical signal and an audio signal to a patient-external device. However, the visual displays of Figs. 6a-e discussed in column 23 are graphical depictions of combinations of input variables and/or parameters. The sound pickups are "pressure or sound pickups" that have a relationship to measured values having a relationship to mechanical contractions. These physiological measured or input variables are converted and digitally processed. *See, e.g.*, column 8, lines 5-18. There is no indication that an audio signal is generated or communicated to the control unit. Thus, the asserted sound pickups and data picked up by acoustic receivers do not correspond to the claimed audio signal, and there is no indication that such data is communicated to a patient-external location as audio signals.

In another attempt to show correspondence to the claimed audio signal, the Examiner has also relied upon Schaldach's mention of using a microphone. First, the use of a microphone to detect a variable does not, in any way, indicate that an audio signal is communicated to an external device. Second, Schaldach teaches using a microphone in an error recognition device to detect respiration rate and a patient's coughing – not cardiac non-electrophysiologic activity. *See, e.g.*, column 20, lines 20-30. Further, using a microphone to detect stroke volume involves detecting pressure in the form of sound waves and does not indicate that an audio signal is produced or communicated to an external device.

Appellant's careful review of Schaldach reveals no teaching or suggestion that any audio signal or other signal containing audio signal information is telemetered to a patient-external device along with a cardiac electrical signal. The reason for this absence of teaching

appears clear, given the use of the signals derived from Schaldach's measured value pickups 117-120. The signals derived from the measured value pickups 117-120 are used to control pacing, including pacing rate. In particular, Schaldach, at column 20, lines 67-68, describes that the pressure or sound pickups measure stroke volume which is used in controlling pacing, including pacing rate.

Thus, any alleged audio signals in measured value pickups 117-120 are used to control pacing and are not described as being of interest beyond the context of pacing control. There is simply no teaching or suggestion by Schaldach that an audio signal is communicated outside the body by the disclosed device. Schaldach only teaches that a microphone may be used to derive measured values such as stroke volume, but does not teach that an audio signal of the type contemplated in Appellant's claims is produced from the microphone, or that any such audio signal is stored and/or communicated to a patient-external device.

The Examiner's reliance upon Schaldach is misplaced as Schaldach does not provide the requisite evidence of correspondence to maintain a §102 rejection. The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). *See, also*, MPEP §2121.01. Moreover, an objective reading of Schaldach reveals that the identical invention as is recited in Appellant's claims is not "shown in as complete detail as is contained in the ... claim," which, as stated above, is a requirement for establishing *prima facie* anticipation. Further, MPEP §2131 states that various portions of a reference cannot be asserted together to anticipate a claim unless the reference arranges the limitations as they are arranged in the claim. Schaldach clearly does not teach an arrangement of its features that would correspond to the subject matter of Appellant's independent claims 1, 17, 32, and 44.

1. Independent Claim 17

Claim 17 further includes limitations that are not taught by Schaldach. For example, Claim 17 recites a patient-external device including a user interface "configured for providing a visual output representative of the cardiac electrical signal and an audio output representative

of the audio signal." The control unit 150 described by Schaldach, at least, does not produce an audio output representative of the audio signal.

The Examiner's assertion that "The term 'audio' can reasonably be interpreted as an electrical or visual manifestation of the mechanical vibrations that are 'sound.'" is unsupported and illogical. The Examiner's definition of audio, "of or relating to the broadcasting, reception, or reproduction of sound" does not encompass a visual manifestation. The instant claims and Specification clearly discern, in accordance with the common understanding of the terms "visual" and "audio," that the terms refer to discrete output modes. For example, Claim 17 recites a "user interface configured for providing a **visual output** representative of the cardiac electrical signal and an **audio output** representative of the audio signal." Appellant maintains that a visual output is an output that can be seen and an audio output is an output that can be heard. Further, Claim 18, which is dependent on Claim 17, differentiates the above audio output by reciting "the user interface is configured for providing a visual output representative of the audio signal." Thus, by claim differentiation, the audio output of the audio signal recited in Claim 17 is different from the visual output of the audio signal recited in claim 18. Schaldach does not teach or suggest a user interface that provides an audio output as recited in Claim 17, and no evidence has been presented to show otherwise.

Appellant respectfully asserts that Schaldach's description of a rate-adaptive pacemaker is insufficient to support the Examiner's rejection of Appellant's independent Claims 1, 17, 32, and 44. It is unclear how one skilled in the art could arrive at Appellant's claimed structure and functionality using Schaldach's rate-adaptive pacemaker teachings without undue experimentation, particularly in the clear absence of a teaching of telemetering an audio signal or other signal containing audio signal information to a patient-external device along with a cardiac electrical signal.

Dependent Claims 2, 3, 5-7, 9, 10, 12, 13, 16, 17, 19-21, 25, 30, 35, 37-39, 41, 45 and 46 depend from independent Claims 1, 17, 32 and 44, respectively, and also stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schaldach. While Appellant does not acquiesce with the particular rejections to these dependent claims, these rejections are also improper for the reasons discussed above in connection with independent Claims 1, 17, 32, and

44. These dependent claims include all of the limitations of their respective base claims and any intervening claims and recite additional features which further distinguish these claims from the cited reference. Therefore, the rejection of dependent Claims 2, 3, 5-7, 9, 10, 12, 13, 16, 35 and 37-39 is improper.

2. Dependent Claim 35

Appellant maintains the traversal of the rejection of dependent Claim 35 because Schaldach does not teach that a characteristic field comprises an acceleration signal. Any accelerometer signal taught by Schaldach is used to detect patient activity, and an indication of patient activity, not an actual acceleration signal, is used in connection with the "characteristic field." *See, e.g.*, Schaldach column 20, lines 12-17: "A digital activity sensor 522 furthermore recognizes, by the appearance of accelerations and decelerations beyond a predetermined threshold value, whether the patient at the time is generally at rest or in motion and switches the characteristic field located in block 520 over accordingly." There is no teaching in Schaldach that accelerometer signals used to indicate patient motion are of sufficient frequency to constitute audible signals perceivable by the human ear. The Examiner's contention that the acceleration signals generated by patient movement in Schaldach meet Appellant's recitation of audio signals produced by the accelerometer recited in Claim 35 is unsupported speculation.

3. Dependent Claims 30 and 38

Regarding the rejection of Claims 30 and 38, Appellant respectfully asserts that the cited portion of Schaldach does not teach that signals are time correlated. Signals are not time correlated merely by virtue of the fact that they are concurrently displayed. One skilled in the art would not interpret the term "time correlated" to mean that two signals are displayed on a monitor at the same time. Column 20, line 46 and the cited portion of column 23 of Schaldach merely teaches that two characteristic fields may be superimposed but does not teach that these two characteristic fields are time correlated as it would be understood by a skilled artisan.

With respect to the rejection of dependent Claims 25 and 30, Appellant notes that if the §102(b) rejection of independent Claim 17 is reversed, the rejection of Claims 25 and 30 must also be reversed. Dependent Claims 25 and 30 are only rejected on the basis of §102(b), thus,

if their underlying independent Claim 17 is not anticipated by Schaldach, dependent Claims 25 and 30 cannot be anticipated.

Appellant submits that Schaldach does not teach, nor has the Examiner shown that Schaldach teaches, each of the claimed limitations of the above discussed independent claims and consequently dependent claims; therefore, the rejection is improper and should be reversed.

**B. The rejection under 35 U.S.C. §103(a) of Claims 17, 19-21, 41, 45 and 46 fails to correspond to the claimed invention and the requisite evidence of motivation to combine the references as asserted has not been established.**

Appellant respectfully maintains the traversal of this rejection because a *prima facie* case of obviousness has not been presented. In order to satisfy a *prima facie* case of obviousness, the Examiner must at least present a reference, or a combination of references, that corresponds to each of the claimed limitations and evidence of motivation that a skilled artisan would have combined the cited references as asserted. *See, e.g.*, MPEP §2142. Appellant submits that these requirements have not been fulfilled.

For the reasons discussed above in connection with Section A, Appellant respectfully maintains that Schaldach, alone or modified as asserted, fails to teach or suggest each of the claim limitations. Using Claim 17 as an example, Schaldach at least fails to teach a patient-external device having a user interface configured for providing an audio output, as claimed. In an attempt to overcome this deficiency, the Examiner asserts that "it is well known in the art to provide audio signals representative of audio events of the heart, for example, by stethoscope or speaker."

It would appear that the Examiner is impermissibly taking official notice that limitations that are not taught or suggested by Schaldach constitute facts outside of the record which are capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art. Appellant traversed this implied taking of Official Notice and, in accordance with MPEP §2144.03, requested that the Examiner cite a reference in support of the assertion that it is well known to implantably produce and store an audio signal, transfer the audio signal to a patient-external device, and to provide an audio output of the audio signal (the limitations absent in Schaldach) along with the other limitations of Claim 17 and that provides motivation

for modifying Schaldach with such teachings. In reply, the Examiner cited four U.S. Patents, none of which teaches the above absent limitations or provides motivation for modifying Schaldach to include such limitations. For example, U.S. Patent No. 5,010,899 is directed to a surgical drape and appears to be entirely unrelated to the instant invention as it makes no mention of terms such as "audio" and "sound." U.S. Patent Nos. 5,737,429 and 4,220,160 are directed to devices for hearing heart sounds but do not address any implantable devices. U.S. Patent No. 4,362,164 is directed to a stethoscope that uses an implanted microphone where the sound is detected outside the body and no implantable storage is discussed. None of the asserted evidence provided by the Examiner supports the Examiner's proposed modification of Schaldach to include implantably producing and storing an audio signal, transferring the audio signal to a patient-external device, and providing an audio output of the audio signal. The Examiner's implied taking of Official Notice fails to overcome the deficiencies of Schaldach. Therefore the proposed modification of Schaldach fails to correspond to each of the claimed limitations, and the rejection is improper.

Further, the Examiner's assertion to introduce a stethoscope or a speaker to the teachings of Schaldach would not result in a combination that corresponds to the claimed invention. For example, a stethoscope, although capable of amplifying cardiac sounds and producing an acoustic signal, is not implantable and does not produce an audio signal that can be stored and transferred. Also, a speaker only produces sound when driven with an audio signal. As set forth in the arguments above, Schaldach does not teach that an audio signal is produced, stored or transferred, therefore, no sound would be generated by the speaker suggested by the Examiner. Without a presentation of correspondence to each of the claimed limitations, the §103(a) rejection is improper and should not be upheld.

In addition to having to show that the cited combination of references teaches or suggests all of the claim limitations, the Examiner must show evidence of motivation to combine these references. Appellant respectfully maintains that this requirement has not been met either.

The Examiner proposes modifying Schaldach to provide an audio output "in order to provide a means to quickly diagnose cardiac maladies by ear." As discussed above, Schaldach is not directed to diagnosis of heart conditions, but rather, to controlling an implanted cardiac pacemaker. No evidence has been provided that a skilled artisan would have used the teachings

of Schaldach to diagnose cardiac maladies. Without a presentation of evidence of motivation to modify Schaldach as asserted, the §103(a) rejection is improper and should not be upheld.

The examiner must show some objective teaching leading to the asserted modification. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). Since Schaldach does not teach any outputting of an audio signal, as discussed above, it is respectfully submitted that the teachings of Schaldach would have provided insufficient guidance for a skilled artisan having this reference before him/her to make the modification suggested by the Examiner. Appellant respectfully asserts that the Examiner's conclusion of obviousness is, instead, based on improper hindsight reasoning using knowledge gleaned only from Appellant's disclosure. As stated by the Federal Circuit:

> Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight.

*In re Dembiczak*, 50 USPQ2d 1614, (Fed. Cir. 1999) (*citing Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985)). Without a suggestion of the desirability of "the combination," a combination of such references is made in hindsight, and the "range of sources available, however, does not diminish the requirement for actual evidence." *Id.* It is a requirement that actual evidence of a suggestion, teaching or motivation to combine prior art references be shown and that this evidence be "clear and particular." *Id.* Broad conclusory statements regarding the teaching of multiple references, standing alone, are not evidence. *Id.*

Appellant respectfully submits that the asserted modification simply does not contemplate the proposed combination of teachings. This piecemeal selection of elements is tantamount to mixing teachings out of context. Such a rejection is not permissible under §103. *See In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000) (proposed modification must not be made in the abstract but rather made in view of the entire teaching of the prior art).

Because the asserted references fail to teach or suggest several of the above-identified limitations, and because the requisite evidence to support the modification of Schaldach as asserted has not been presented, Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented. Appellant accordingly requests that the rejection be reversed.

**C. The rejection of dependent Claims 4 and 36 is improper because the asserted combination of Schaldach and Turcott fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.**

Appellant respectfully maintains the traversal of the rejection of dependent Claims 4 and 36 for reasons similar to those discussed above in Section A. Schaldach fails to teach certain limitations of independent Claims 1 and 32 (from which Claims 4 and 36 depend), and the Examiner's reliance on the teachings of Turcott fail to overcome these deficiencies.

Moreover, the Examiner has not provided the requisite evidence of motivation to combine the cited references as asserted. The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a piezoelectric transducer with an implantable housing to provide an inexpensive mechanical-to-electrical transducer that is sensitive to a frequency band within the limits of human hearing and human heart sounds." However, this is not evidence of motivation to combine a piezoelectric transducer with the teachings of Schaldach but rather, is a generalized statement of what is asserted as being taught by Turcott. No evidence has been provided that a skilled artisan would have attempted to introduce a piezoelectric transducer to the teachings of Schaldach. Thus, no evidence has been presented in support of the asserted combination rendering the rejection improper. Appellant accordingly requests that the rejection be reversed.

**D. The rejection of dependent Claims 8, 11 and 40 is improper because the asserted combination of Schaldach and Kadhiresan fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.**

Appellant respectfully maintains the traversal of the rejection of dependent Claims 8, 11 and 40 for reasons similar to those discussed above in Section A. Schaldach fails to teach certain limitations of independent Claims 1 and 32 (from which Claims 8, 11 and 40 depend), and the Examiner's reliance on the teachings of Kadhiresan fail to overcome these deficiencies.

Moreover, the Examiner has not provided the requisite evidence of motivation to combine the cited references as asserted. The Examiner asserts that "it would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide

an implantable device with a heart motion detector, which is implanted subcutaneously and in a non-intrathoracic location to simplify the implantation and a lead to connect the electrodes to the housing." However, this is not evidence of motivation to combine a subcutaneous, non-intrathoracic electrode with the teachings of Schaldach but rather, is a generalized statement of what is asserted as being taught by Kadhiresan. No evidence has been provided that a skilled artisan would have attempted to introduce a subcutaneous, non-intrathoracic electrode to the teachings of Schaldach. Thus, no evidence has been presented in support of the asserted combination rendering the rejection improper. Appellant accordingly requests that the rejection be reversed.

**E. The rejection of dependent Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 is improper because the asserted combination of Schaldach and Gessman fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.**

Appellant respectfully maintains the traversal of the rejection of dependent Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 for reasons similar to those discussed above in Section A. Schaldach fails to teach certain limitations of independent Claims 1, 17, 32 and 44 (from which Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 depend), and the Examiner's reliance on the teachings of Gessman fail to overcome these deficiencies.

Moreover, the Examiner has not identified where Gessman teaches each of the limitations of the rejected claims, and Gessman does not teach such limitations. The Examiner merely cites column 4, line 57 as corresponding to each of the limitations of the ten rejected claims. Appellant notes that 35 U.S.C. §132 requires that when any claim is rejected, the reasons for such rejection should be presented "together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application." The lack of citations to specific portions of the asserted reference makes it difficult to ascertain whether Gessman corresponds to the asserted teachings. For example, Appellant fails to recognize where Gessman teaches at least a user interface providing a visual output representative of an audio signal (Claim 18) and circuitry telemetering a cardiac electrical signal and an audio signal in response to a request by the patient-external device (Claim 23).

The remote unit 10 of Gessman appears to receive data only after a shock is administered. The Examiner has acknowledged that Schaldach fails to teach the limitations of the rejected claims and Gessman also does not appear to teach each of these claims; thus any combination of these references must also fail to correspond to the claimed limitations.

Further, the Examiner has not provided the requisite evidence of motivation to combine the cited references as asserted. The Examiner asserts that since Gessman allegedly teaches the limitations of the rejected claims, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify Schaldach to include such teachings. However, this is not evidence of motivation to combine these teachings with the teachings of Schaldach but rather, is a generalized statement of what is asserted as being taught by Gessman. No evidence has been provided that a skilled artisan would have attempted to introduce the asserted teachings to the teachings of Schaldach. Thus, no evidence has been presented in support of the asserted combination rendering the rejection improper. Appellant accordingly requests that the rejection be reversed.

**F. The rejection of dependent Claims 15, 26-29, 42 and 48 is improper because the asserted combination of Schaldach and Riff fails to teach or suggest each of the claimed limitations and the requisite evidence of motivation to combine the references as asserted has not been established.**

Appellant respectfully maintains the traversal of the rejection of dependent Claims 15, 26-29, 42 and 48 for reasons similar to those discussed above in Section A. Schaldach fails to teach certain limitations of independent Claims 1, 17, 32 and 44 (from which Claims 15, 26-29, 42 and 48 depend), and the Examiner's reliance on the teachings of Riff fail to overcome these deficiencies.

Moreover, the Examiner has not provided the requisite evidence of motivation to combine the cited references as asserted. The Examiner asserts that since Riff allegedly teaches the limitations of the rejected claims, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify Schaldach to include such teachings. However, this is not evidence of motivation to combine these teachings with the teachings of Schaldach but rather, is a generalized statement of what is asserted as being taught by Riff. No

evidence has been provided that a skilled artisan would have attempted to introduce the asserted teachings to the teachings of Schaldach. Thus, no evidence has been presented in support of the asserted combination rendering the rejection improper. Appellant accordingly requests that the rejection be reversed.

## VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited references and that the rejections of claims 1-48 should be reversed. Appellant respectfully requests reversal of the rejections as applied to the appealed claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

Respectfully submitted,

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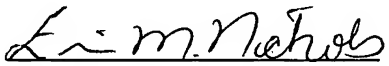

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## CLAIMS APPENDIX

1. An implantable device, comprising:

an implantable housing;

a plurality of implantable electrodes coupled to the housing and configured for sensing cardiac electrical activity;

detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity;

an implantable sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement;

sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal;

memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal;

a controller provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry; and

communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal to a patient-external device.

2. The device of claim 1, wherein the sensor comprises an accelerometer.

3. The device of claim 1, wherein the sensor is configured to sense pressure waves produced by the heart movement.

4. The device of claim 1, wherein the sensor comprises a piezoelectric transducer.

5. The device of claim 1, wherein the sensor comprises a microphone.

6. The device of claim 1, wherein the sensor is situated in or on the housing.

7. The device of claim 1, further comprising a lead wherein the sensor is provided in or on the lead.

8. The device of claim 1, wherein at least one of the plurality of electrodes is configured for subcutaneous, non-intrathoracic placement.

9. The device of claim 1, wherein at least one of the plurality of electrodes is configured for intrathoracic placement.

10. The device of claim 1, wherein at least one of the plurality of electrodes is disposed in or on the housing.

11. The device of claim 1, further comprising a lead wherein at least one of the plurality of electrodes is supported by the lead configured for subcutaneous, non-intrathoracic placement, the lead coupling the at least one of the plurality of electrodes to the housing.

12. The device of claim 1, further comprising energy delivery circuitry coupled to the controller and at least some of the plurality of electrodes, the energy delivery circuitry configured to deliver a cardiac therapy.

13. The device of claim 12, wherein the cardiac therapy comprises a cardiac pacing therapy.

14. The device of claim 12, wherein the cardiac therapy comprises a cardiac defibrillation therapy.

15. The device of claim 1, further comprising a patient actuatable trigger configured to communicate a trigger signal to the controller via the communications circuitry, the controller initiating storing of the cardiac electrical signal and the audio signal in the memory in response to the trigger signal.

16. The device of claim 1, wherein at least one of the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device in response to a trigger signal.

17. A medical system, comprising:

a patient-implantable device, comprising:

a housing;

a plurality of electrodes coupled to the housing and configured for sensing cardiac electrical activity;

detection circuitry provided in the housing and coupled to at least some of the plurality of electrodes, the detection circuitry producing a cardiac electrical signal in response to the sensed cardiac electrical activity;

a sensor configured to sense movement of a heart and produce a sensor signal in response to the sensed heart movement;

sensor circuitry provided in the housing and coupled to the sensor, the sensor circuitry configured to produce an audio signal in response to the sensor signal;

memory provided in the housing and coupled to the detection circuitry and sensor circuitry, the memory configured to store the audio signal and the cardiac electrical signal;

a controller provided in the housing and coupled to the memory, detection circuitry, and sensor circuitry; and

communications circuitry provided in the housing and coupled to the controller, the communications circuitry configured to telemeter the cardiac electrical signal and the audio signal; and

a patient-external device comprising:

patient-external communications circuitry configured to receive the cardiac electrical signal and the audio signal telemetered from the patient-implantable device; and

a user interface coupled to the patient-external communications circuitry, the user interface configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal.

18. The system of claim 17, wherein the user interface is configured for providing a visual output representative of the audio signal and an audio output representative of the cardiac electrical signal.

19. The system of claim 17, wherein the user interface comprises a display configured to display a representation of one or both of the cardiac electrical signal and the audio signal.

20. The system of claim 17, wherein the user interface comprises a display configured to display one or both of textual and graphical information associated with one or both of the cardiac electrical signal and the audio signal.

21. The system of claim 17, wherein the user interface comprises an audio output device configured to broadcast the audio signal.

22. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a user request.

23. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in response to a request by the patient-external device.

24. The system of claim 17, wherein the communications_circuitry is configured to telemeter the cardiac electrical signal and the audio signal from the patient-implantable device to the patient-external device in real-time.

25. The system of claim 17, wherein the patient-external device further comprises a storage media to store the cardiac electrical signal and the audio signal telemetered from the patient-implantable device.

26. The system of claim 17, further comprising a server communicatively coupled to one of the patient-implantable device and the patient-external device.

27. The system of claim 17, further comprising a server communicatively coupled to the patient-implantable device and the patient-external device.

28. The system of claim 17, further comprising a server communicatively coupled to the patient-implantable device and the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the server and communicated from the server to the patient-external device.

29. The system of claim 17, further comprising a server communicatively coupled to the patient-external device, wherein the cardiac electrical signal and the audio signal are telemetered from the patient-implantable device to the patient-external device and communicated from the patient-external device to the server.

30. The system of claim 17, wherein at least one of the patient-implantable device and patient-external device provides a time correlation between the cardiac electrical signal and the audio signal.

31. The system of claim 30, wherein the user interface comprises:

a speaker configured to broadcast the audio signal; and

a display configured to display a representation of the cardiac electrical signal and indicia indicative of the time correlation.

32. A method, comprising:

sensing, from within a patient, movement of a heart and producing a sensor signal in response to the sensed heart movement;

producing, within the patient, an audio signal using the sensor signal;

detecting, within the patient, cardiac electrical activity and producing a cardiac electrical signal in response to the detected cardiac electrical activity;

storing, within the patient, the audio signal and the cardiac electrical signal; and

telemetering the audio signal and cardiac electrical signal to a patient-external location.

33. The method of claim 32, wherein the audio signal and cardiac electrical signal are telemetered to the patient-external location in response to a trigger signal generated by a patient-actuated device.

34. The method of claim 32, wherein the audio signal and cardiac electrical signal are telemetered to a patient-external system in response to a trigger signal generated by the patient-external system.

35. The method of claim 32, wherein the sensor signal comprises an accelerometer signal.

36. The method of claim 32, wherein the sensor signal comprises a piezoelectric transducer signal.

37. The method of claim 32, wherein the sensor signal comprises a microphone output signal.

38. The method of claim 32, wherein storing comprises time correlating the audio signal and the cardiac electrical signal.

39. The method of claim 32, wherein detecting comprises detecting the cardiac electrical activity intrathoracically.

40. The method of claim 32, wherein detecting comprises detecting the cardiac electrical activity from one or more subcutaneous, non-intrathoracic locations.

41. The method of claim 32, further comprising broadcasting the audio signal and displaying a representation of the cardiac electrical signal.

42. The method of claim 32, further comprising communicating the audio signal and the cardiac electrical signal to a server system.

43. The method of claim 32, further comprising telemetering the detected sensor signal and cardiac electrical signal in real-time.

44. An implantable device, comprising:

means for detecting a cardiac electrical signal;

means for detecting cardiac non-electrophysiologic activity transduceable to an audio signal;

means for storing the cardiac electrical signal and the audio signal within a patient; and

means for communicating the cardiac electrical signal and the audio signal to a patient-external location.

45. The device of claim 44, further comprising means for playing back the cardiac electrical signal and the audio signal.

46. The device of claim 44, further comprising means for concurrently displaying a representation of the cardiac electrical signal and broadcasting the audio signal.

47. The device of claim 44, further comprising means for concurrently displaying a representation of the detected cardiac electrical signal and broadcasting the detected audio signal in real-time.

48. The device of claim 44, further comprising means for providing server access to the cardiac electrical signal and the audio signal.

## EVIDENCE APPENDIX

None.

## RELATED PROCEEDINGS APPENDIX

None.